BIOMET
MANUFACTURING CORP.

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive Warsaw, IN 46581-0857
Phone number	(574) 267-6639
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Tracy Bickel Johnson, RAC
Date prepared	January 14, 2014
Name of device	
Trade or proprietary name	Vanguard™ XP Knee System
Common or usual name	Knee Prosthesis
Classification name	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (§888.3565) Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (§888.3560) Knee joint patellofemorotibial semi-constrained UHMWPE pegged uncemented polymer/metal/polymer (§888.3560) Knee joint patellofemorotibial polymer+Additive/metal/polymer +Additive semi-constrained cemented prosthesis (§888.3560)
Classification panel	Orthopedic
Regulation	21CFR §888.3565 21CFR §888.3560
Product Code(s)	JWH, MBH, MBV, OIY
Legally marketed device(s) to which equivalence is claimed	K113550 Vanguard™ Knee System (JWH, MBH, OIY) K102580 Vanguard™ Removable Molded Poly Tibia (JWH) K080528 E1™ Tibial Bearings (OIY, JWH, MBH, MBV) K904448 Townley Total Knee (JWH) K833363 Cloutier II Fiber Metal Total Knee (JWH) K031061 NexGen® Total Knee System (MBH) K050222 Vanguard™ Anterior Stabilized Tibial Bearings

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	(JWH, MBH) K961021 Kirschner Knee Modified (JWH) K921182 Ultra High Molecular Weight Polyethylene (JWH, HRY) K993159 Maxim Knee System (JWH)
Reason for 510(k) submission	Additional Vanguard® product line to include an XP femoral, ACL/PCL and PCL tibial tray, tibial bearings (AS, XP) and associated instrumentation.
Device description	The Vanguard XP Knee System is a total knee replacement system that consists of a femoral component composed of Co-Cr-Mo, two styles of tibial trays/plates manufactured of Co-Cr-Mo (with locking bar), and dual bearings machined of E1 poly. Biomet® patellae can be used with the Vanguard XP Knee System. Both the XP femoral and the XP-CR tibial components are available with a previously cleared porous plasma spray (PPS) coating of titanium alloy and Biomet's Interlok® coarse blasted finishes. The Vanguard XP-XP tibial components are available in Biomet's Interlok® coarse blasted finish. Porous coated femoral and tibial components are indicated for cemented and uncemented biological fixation application. Non-coated coarse blasted (Interlok®) femoral and tibial components are indicated for cemented application only. Accessory components are available including removable femoral pegs and femoral augments.
Intended use of the device	The Vanguard™ XP Knee System is intended for replacement of a total knee joint and the preservation of the anterior and/or posterior cruciate ligament (ACL/PCL) when used in conjunction with a femoral, tibial and patellar component.
Indications for use	Specific indications are as follows: 1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved. 2. Correction of varus, valgus, or posttraumatic deformity. 3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous total joint replacement procedure. Femoral components and tibial tray components with porous coatings are indicated for cemented and un-cemented

	biological fixation application. Non-coated (Interlok®) devices and all polyethylene patellar components are indicated for cemented application only. Regenerex components are intended only for uncemented biologic fixation application.

Summary of the Technologies

The Vanguard™ XP Knee System is made up of multiple components, including: instrumentation, femoral components, several types of bearings and tibial trays.

The technological characteristics of the Vanguard™ XP Knee System are the same as those of predicate devices (K113550, K102580, K080528, K050222, K904448, K833363, and K031061) in terms of design, material, and principle of operation with the exception of slight modifications as described in this 510(k). The femoral and tibial components of the Vanguard™ XP Knee System utilize the identical manufacturing processes as the predicates (K113550, K080528, and K102580). The previously provided porous plasma spray characterization data in K113550 was used in support of this 510(k). The porous plasma spray coating on the ASTM F75 substrate is for both cemented and uncemented, biologic fixation. Non-clinical testing was conducted to demonstrate that the differences did not adversely affect safety and efficacy, and to demonstrate substantial equivalence to the predicate components. All testing met or exceeded the established acceptance criteria. This information is detailed below in the Performance (Non-clinical) section.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS

Performance Test Summary-New Device

The following tests were performed for the new Vanguard® XP Knee System:

- Tibiofemoral Mechanical Stability
- Static Locking Mechanism
- Fixation and Cyclic Locking Mechanism
- Wear Test
- Cyclic Fatigue of Tibial Tray
- Surface Roughness Analysis
- Tibiofemoral Constraint
- Tibiofemoral Contact Area
- Femoral Section Analysis
- ROM Analysis
- Tibial/Bearing Assembly
- MRI Analysis and Justification
- Surgical Instrument Cadaver Validations
- Bearing Fatigue Tests

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF

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SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
Clinical Performance Data/Information: N/A

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
No clinical testing was necessary for a determination of substantial equivalence. The results of mechanical testing indicated the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2013

Biomet, Incorporated
% Ms. Tracy Bickel Johnson, RAC
Global Regulatory Project Manger
56 East Bell Drive
Warsaw, Indiana 46581

Re: K122160
Trade/Device Name: Vanguard™ XP Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, MBV, OIY
Dated: March 8, 2013
Received: March 11, 2013

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122160

Device Name: Vanguard™ XP Knee System

Indications For Use:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous total joint replacement procedure.

Femoral components and tibial tray components with porous coatings are indicated for cemented and uncemented biological fixation application. Non-coated (Interlok®) devices and all polyethylene patellar components are indicated for cemented application only. Regenerex components are intended only for uncemented biologic fixation application.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopaedic Devices